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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,255	02/14/2001	Bruce Marvin Held	N1205-009	1482

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EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/06/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/782,255

Applicant(s)
Held et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 8, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Feb 14, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Amendments to the claims in Paper No. 8, filed July 8, 2002 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.
2. Amendments to the specification in Paper No. 8 have overcome the objection to the specification in the previous office action, and the objection is withdrawn.
3. Arguments regarding the rejection of claims 36-42 in Paper No. 8 have overcome the rejection of the claims under 35 USC 102 over US 6,162,641 in the previous office action, and the rejection is withdrawn.
4. Arguments filed in Paper No. 8 regarding the rejection of the claims under 35 USC 102 over each of Xu et al., Dickson et al., Shibui et al., US 5,847,102, US 5,959,094, US 6,214,614, US 6,322,962, or US 6,118,049 have been fully considered but they are not persuasive. The response to the arguments is contained in the rejection repeated below.
5. The requirement for the submission of formal drawings has not been met and is considered non-responsive.

Drawings

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6. This application has been filed with informal drawings which are acceptable for examination purposes only.
7. New formal drawings are required in this application because the 8th edition of MPEP, 608.02(b) no longer permits drawings to be held in abeyance. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 36-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al. (see especially materials and methods and the figures).

Xu et al. taught a method of making a hybrid promoter by combining known sequences from known promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested for improved promoter activity. At least 15% of the known sequences have been changed in the making of the hybrid

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promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

Response to Arguments

10. Arguments set forth in Paper No. 8 assert that Xu et al. do not disclose constructing a malic promoter which is about 80% homologous over the entire length of the wild type malic promoter.

There is no limitation in claims 36-42 regarding 80% homology. Therefore the argument is not found convincing.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Dickson et al. (see especially the materials and methods and the figures) or Shibui et al. (see especially the materials and methods and the figures) .

Each of Dickson et al. or Shibui et al. taught a method of making a hybrid promoter by combining known sequences from known promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested for improved promoter activity. At least 15% of the known sequences have been changed in the

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making of the hybrid promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

Response to Arguments

12. Arguments set forth in Paper No. 8 assert that Dickson et al. and Shibui et al. do not disclose constructing a promoter which is about 80% homologous over the entire length of the wild type promoter.

There is no limitation in claims 36-42 regarding 80% homology. Therefore the argument is not found convincing.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

13. Claims 36-42 are rejected under 35 U.S.C. 102(e) as being anticipated by each of US 5,847,102 (see especially the abstract, summary and figures), US 5,959,094 (see especially the abstract, summary and figures), US 6,214,614 (see especially the abstract, summary, the claims and figures), US 6,322,962 (see especially the abstract, summary, columns 32-33 and figures), or US 6,118,049 (see especially the abstract, summary, columns 9-11 and figures).

Each of US 5,847,102, US 5,959,094, US 6,214,614, US 6,322,962, or US 6,118,049 taught a method of making a hybrid promoter by combining known sequences from known

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promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested for improved promoter activity. At least 15% of the known sequences have been changed in the making of the hybrid promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

Response to Arguments

14. Arguments set forth in Paper No. 8 assert that each of US 5,847,102 or US 5,959,094 do not disclose constructing a promoter which is about 80% homologous over the entire length of the wild type promoter.

There is no limitation in claims 36-42 regarding 80% homology. Therefore the argument is not found convincing.

15. Arguments set forth in Paper No. 8 assert that US 6,214,614 does not disclose constructing a promoter but rather a repressor element.

Figures 5-7, 13 and 14 in US 6,214,614 describe the construction of synthetic promoter elements as recited in the rejection above. Therefore the argument is not found convincing.

16. Arguments set forth in Paper No. 8 assert that US 6,118,049 does not disclose constructing a promoter which is a homolog to either the E4 or E8 promoter.

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US 6,118,049 describes a method of constructing a hybrid promoter which fulfills the requirement of sections (c) and (d) of claim 36, namely selecting segments of a known (E4 or E8) promoter which are similar to the known promoter (either E4 or E8) and aligning the segments in linear order. Therefore the argument is not found convincing.

17. Arguments set forth in Paper No. 8 assert that US 6,322,962 does not disclose constructing a synthetic homologous promoter.

US 6,322,962 teaches at columns 32-33 constructing synthetic promoters by selecting segments of a known promoter which are similar to the known promoter and aligning the segments in linear order. Therefore the argument is not found convincing.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

November 3, 2002


TERRY MCKELVEY
PRIMARY EXAMINER